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10/597,847

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Philipp Kropf

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EXAMINER

YARNALL, MEGAN LEIGH

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,847	<b>Applicant(s)</b> KROPF ET AL.	
	<b>Examiner</b> MEGAN YARNALL	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 3/6/08 have been fully considered but they are not persuasive. Applicant argues that amended claims 18, 36 and 39 are not anticipated by Lakin because they now state that the second cavity is "adapted to" receive the bone end. However, while Lakin does not designate the second cavity to be for receiving bone, the structure is the same as that claimed and is capable of receiving bone depending on the intended use of the device. Regarding the added limitation of the shell section comprising less than a hemisphere, Lakin teaches minimizing the amount of bone that needs to be removed (par.7) and discloses that the shell may be a full, greater than full, or partial hemisphere (par.32) depending on the requirements for a particular patient.

2. Applicant's arguments regarding the length of the crown are not persuasive. It is well within the skill of one of ordinary skill in the art to modify the length of the crown as adjusting the length yields predictable results including minimizing or maximizing the depth of the crown depending on the desired result. For instance if the patient has a large area of problematic tissue requiring more resection, a larger crown may be necessary. Alternatively, using a shorter crown results in less bone resection and may be possible if the patient's bone can withstand a smaller crown. It is also noted that several claims in the application (claims 37 and 38) actually specify that the crown extends beyond the plane of the shell. Sutter is structurally identical to Applicant's

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invention with the exception of shell size and crown length, both of which are obvious to modify to reduce the amount of bone resection.

***Claim Objections***

3. Claim 42 is objected to because of the following informalities: claim 42 refers to the prosthesis of claim 1 but claim 1 is canceled. As claim 18 is the first claim in the claims, the Examiner believes "claim 1" in line 2 of claim 42 is in error for --claim 18-- and has been examined as such. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 18, 36, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Lakin 2003/0163202.

6. Re claim 18, Lakin teaches prosthesis 10 for replacing a surface in an area of a ball of a ball-and-socket joint comprising: spherical shell section 12 having outer surface 16 that is configured to lie in an articular fossa and attachment to a surface, shell section 12 having cavity 18 for receiving a bone end (par.32), and crown 20 that partitions cavity 18 of shell section 12 into a first and second cavities capable of receiving the bone end (fig.1), wherein the shell section comprises less than a hemisphere (par.32, ll.3-5) and a free edge of crown 20 lies in the same plane as a free edge of shell section 12 (fig.9).

7. Re claim 36, Lakin teaches prosthesis 10 for replacing a surface in an area of a ball of a ball-and-socket joint comprising: spherical shell section 12 having outer surface 16 that is configured to lie in an articular fossa and attachment to a surface, shell section 12 having cavity 18 for receiving a bone end (par.32); and crown 20 that partitions cavity 18 of shell section 12 into a first and second cavities capable of receiving portions of the bone end (fig.1); wherein the shell section comprises less than a hemisphere (par.32, ll.3-5) and a free edge of crown 20 is displaced from a plane in which a free edge of shell section 12 lies (fig.1).

8. Re claim 39, Lakin further teaches prosthesis 10 wherein the free edge of crown 20 does not intersection the plane in which the free edge of shell section 12 lies (fig.1).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 19-21, 35, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lakin 2003/0163202.

11. Re claims 19-21, Lakin teaches the invention substantially as claimed and as discussed above. Lakin further discloses a spherical shell section wherein shell component 12 can be a partial hemisphere (par.32, ll.4-6). This means the shell height may be less than 100% of the radius of the ball. While Lakin does not specifically disclose a shell height that is about 65-90%, 70-85%, or 80% of the radius of the ball, it

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would be have been obvious to one of ordinary skill in the art at the time of the invention as it has been held that it is not inventive to discover the optimum or workable ranges by routine experimentation and would be an obvious extension of prior art teachings (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A).

12. Re claim 35, Lakin teaches the invention as claimed and as discussed above. Lakin further teaches a screw locking mechanism for coupling two components (par.34, II.1-4). While the location of the threads is not positively disclosed as being on an outer surface of the crown and/or the inner surface of the shell section, it would have been a matter of design choice to place the threads in either location, which a person of ordinary skill in the art would have found obvious as they were not disclosed as being critical to the practice of the invention (In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) MPEP 2144.04 IV B). Further, it has been held that making parts separable for any desirable reason is an obvious extension of prior art teachings (In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) MPEP V C).

13. Re claim 40, Lakin teaches the invention substantially as claimed and as discussed above. In figure 1, Lakin discloses prosthesis 10 wherein a free edge of crown 20 is a distance away from the plane containing the free edge of shell section 12. While Lakin does not specifically disclose a distance of up to 5 mm from the plane containing the free edge of the shell section, it has been held that limitations relating to size are not sufficient to patentably distinguish over the prior art (In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) MPEP 2144.04 IV A).

14. Re claim 42, Lakin teaches the invention substantially as claimed and as discussed above. Lakin further teaches a plurality of shells and stems of various diameters in order to allow a surgeon to pick from a variety of components to match the patient's anatomy (par.38). While Lakin does not positively disclose a set wherein the ratio of the height of the shell section to a respective ball diameter is equal for the different prosthesis and a diameter of each crown amounts to the same percentage of a diameter of the spherical shell section, it has been held that changes in shape are a matter of design choice, which a person of ordinary skill in the art would have found obvious as they were not disclosed as being critical to the practice of the invention (In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) MPEP 2144.04 IV B).

15. Claims 18-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter et al. 4,332,036 in view of Lakin 2003/0163202.

16. Re claim 18, Sutter discloses the invention substantially as claimed including prosthesis 1 for replacing a surface in an area of a ball of a ball-and-socket joint comprising: spherical shell section 3 having outer surface 3a that is configured to lie in an articular fossa and attachment to a surface, shell section 3 having cavity 3c for receiving a bone end (fig.14) and crown 7 that partitions the cavity of the shell section into first and second cavities capable of receiving bone (fig.6) wherein the shell is hemispherically shaped and (fig.1). However, Sutter does not disclose that the shell section comprises less than a hemisphere and that a free edge of the crown lies in the same plane as a free edge of the shell section.

Lakin discloses a prosthesis for replacing a surface of a ball in a ball-and-socket joint, in the same field of endeavor, wherein the shell section may be in the form of a partial hemisphere (par.32) for the purpose of providing a partial hip replacement that conserves healthy bone tissue for future revision procedures and minimizes the amount of tissue that is required to be removed (par.8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the hemispherical head of Sutter to be less than hemispherical as taught by Lakin in order to minimize the amount of tissue resection. Regarding the length of the crown, while Sutter discloses the free edge of crown 7 extending beyond the plane of the free edge of shell section 3, it has been held that limitations relating to size are not sufficient to patentably distinguish over the prior art (*In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) MPEP 2144.04 IV A). The teachings of Sutter may also be applied in this instance wherein the crown of Sutter is shortened to be even with the plane of the free edge of the shell as shown by Lakin. Reducing the length of the crown also results in minimizing bone resection.

17. Re claims 19-21, as Sutter in view of Lakin discloses the general conditions of the claims wherein the shell is less than a hemisphere, it would have been obvious to one of ordinary skill in the art to modify the size of the partial hemispherical shell to include the claimed ranges as it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A).



18. Re claim 22, Sutter further teaches prosthesis 1 wherein first cavity 7 has a circular shape and second cavity 3c has an annular shape (fig.1).
19. Re claim 23, Sutter further teaches prosthesis 1 wherein innermost end of the crown 7b is integrally connected to the inner surface of the shell section so as to form a single integral structure (col.3, ll.25-27).
20. Re claim 24, Sutter further teaches prosthesis 1 wherein at least one of the inner surface of the shell section and a surface of the crown is configured for contact with the bone end and is therefore a roughened surface (col.5, ll.46-50).
21. Re claim 25, Sutter further teaches prosthesis 1 wherein the crown has at least one opening 7e formed therein to provide communication between the first and second cavities (fig.1).
22. Re claim 26, Sutter further teaches prosthesis 1 wherein the at least one opening comprises at least five openings (figs.1, 20).
23. Re claim 27, Sutter further teaches prosthesis 1 wherein at least one of an inner surface and an outer surface of the crown has a relief structure formed as a part thereof (col.7, ll.26-31).
24. Re claim 28, Sutter further teaches prosthesis 1 wherein the relief structure comprises a fluting that is formed by ring beads that extend circumferentially around the crown (col.7, ll.26-31; fig.11).
25. Re claim 29, Sutter further teaches prosthesis 1 wherein the inner surface of the shell section includes a relief structure that extends along an edge of the shell section (col.3, ll.53-60; col.6, ll.1-17; figs. 7, 11).

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26. Re claim 30, Sutter further teaches prosthesis 1 wherein the relief structure comprises fluting formed circumferentially around the inner surface of the shell section (figs. 2, 7, 11).

27. Re claim 31, Sutter further teaches prosthesis 1 wherein the crown and shell section are separate parts and are constructed to be securely coupled to one another (col.3, ll.25-27).

28. Re claim 32, Sutter teaches the invention as claimed and as discussed above. Sutter does not teach a prosthesis wherein the crown and shell section are constructed to be threadingly coupled to one another by means of threads formed on at least one of an outer surface of the crown and the inner surface of the shell section.

Lakin teaches a screw locking mechanism for the purpose of coupling two components together (par.34, ll.1-4). While the location of the threads is not positively disclosed as being on an outer surface of the crown and/or the inner surface of the shell section, it would have been a matter of design choice to place the threads in either location, which a person of ordinary skill in the art would have found obvious as they were not disclosed as being critical to the practice of the invention (In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) MPEP 2144.04 IV B). Further, it has been held that making parts separable for any desirable reason is an obvious extension of prior art teachings (In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) MPEP V C).

Therefore, it would have been obvious at the time of the invention to modify Sutter in view of Lakin in order to hold the components together without any appreciable movement as taught by Lakin, par.34, ll.4-6.

29. Re claim 33, Sutter further teaches prosthesis 1 wherein the crown has a circular shape (col.3, l.22).

30. Re claim 34, Sutter further teaches prosthesis 1 wherein the crown is arrayed in a coaxial manner (col.3, ll.22-23; fig.1).

31. Re claim 35, see the rejection of claim 32 above.

32. Re claim 36, Sutter teaches prosthesis 1 for replacing a surface in an area of a ball of a ball-and-socket joint comprising: spherical shell section 3 having outer surface 3a that is configured to lie in an articular fossa and attachment to a surface, shell section 3 having cavity 3c for receiving a bone end (fig.14), and crown 7 that partitions the cavity of the shell section into first and second cavities adapted to receive portions of the bone end (fig.1), wherein shell section 3 is hemispherical (col.3, ll.17-19) and a free edge of the crown is displaced (s) from a plane in which a free edge of shell section 3 lies (fig.3). Regarding the limitation wherein the shell section comprises less than a hemisphere, see section 16 above with respect to the teachings of Lakin for minimizing bone resection with smaller components.

33. Re claims 37 and 38, Sutter further teaches prosthesis 1 wherein the free edge of crown 7 projects by up to 5 mm over the plane in which the free edge of shell section 3 lies. Sutter discloses the diameter of the crown, d, to be equal to 10-25 mm (col.4, ll.8-10), d preferably equal to at least 30% of the length L (col.4, ll.18-20), and projection

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distance,  $s$ , preferably equal to at most 40% of  $L$  (col.4, ll.23-25). From these values  $s$  may range from 0.9-2.25 mm, and is therefore less than 5 mm, or about 1-3mm.

34. Re claims 39 and 40, see section 16 above.

35. Re claim 41, Sutter further teaches a procedure for implantation of a prosthesis in a bone comprising the steps of: preparing the bone and forming a groove in the bone (col.5, ll.4-14; figs. 4, 5); prosthesis 1 for replacing a surface in an area of a ball of a ball-and-socket joint, prosthesis 1 including spherical shell section 3 and crown 7, shell section 3 having outer surface 3a that is configured to lie in an articular fossa and attachment to a surface, shell section 3 having cavity 3c for receiving a bone end (fig.14); crown 7 partitioning the cavity of the shell section into a first cavity and a second cavity (fig.1), wherein a shape of shell section 3 is hemispherical (col.3, ll.17-19) and a free edge of crown 7 lies outside the plane of the free edge of shell section 3 (fig.1); and inserting the prosthesis onto the bone such that the crown is received in the groove formed in the bone (col.5, ll.14-17; fig.6). Regarding the limitations wherein the shell is less than a hemisphere and the crown lies in the same plane as a free edge of the shell, see the rejection of claim 18 in section 16 above.

### ***Conclusion***

36. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEGAN YARNALL whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 7:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. Y./

Examiner, Art Unit 3738

7/10/08

/Bruce E Snow/

Primary Examiner, Art Unit 3738